

What is claimed is:

1. A method for assessing the need for treatment of a subject with an anti-oxidant comprising the steps of:

- a) collecting a sample of body fluid from a subject suspected of needing such treatment;
- b) measuring the amount of lipid peroxide and pyroglutamic acid levels in said sample;
- c) measuring the level of blood plasma glutathione;
- d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard; and
- e) comparing the level of blood plasma glutathione with that of a normal standard; and

wherein the presence of lipid peroxide and pyroglutamic acid in said sample and the blood plasma levels of glutathione are present in amounts that lie outside the normal range are indicative of a need for anti-oxidant treatment.

2. The method of claim 1, wherein said subject in need of treatment with an anti-oxidant also experiences a reduction in immune cell number and/or function.

3. The method of claim 2, wherein said immune cell is selected from the group consisting of a T cell, a B cell or a natural killer cell.

4. The method of claim 3, wherein said T cell is selected from the group consisting of a CD4+ T cell or a CD8+ T cell.

5. The method of claim 1, wherein said anti-oxidant comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

6. The method of claim 1, wherein the sample of body fluid is urine.

7. A method for measuring the effectiveness of therapy with an anti-oxidant in a subject receiving treatment with an anti-oxidant comprising the steps of:

- a) collecting a sample of body fluid from a subject being treated with an anti-oxidant;
- b) measuring the amount of lipid peroxide and pyroglutamic acid in said sample;
- c) measuring the level of blood plasma glutathione;
- d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard;
- e) comparing the level of blood plasma glutathione with that of a normal standard; and

wherein the presence of normal levels of lipid peroxide and pyroglutamic acid in said sample and the presence of normal levels of blood plasma glutathione are an indication of effectiveness of the anti-oxidant therapy.

8. The method of claim 7, wherein said subject receiving treatment with an anti-oxidant also experienced a reduction in immune cell number and/or function prior to the start of therapy with the anti-oxidant.

9. The method of claim 8, further comprising determining whether immune cell number and/or function is normalized in said subject, wherein said normalization is indicative of the effectiveness of therapy with said anti-oxidant.

10. The method of claim 9, wherein said immune cell is selected from the group consisting of a T cell, a B cell or a natural killer cell.

11. The method of claim 10, wherein said T cell is selected from the group consisting of a CD4+ T cell or a CD8+ T cell.

12. The method of claim 7, wherein said anti-oxidant comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

13. The method of claim 7, wherein the sample of body fluid is urine.

14. A method for measuring the utilization efficiency of an anti-oxidant in a subject receiving therapy with an anti-oxidant comprising the steps of:

- a) collecting a sample of body fluid from a subject being treated with an anti-oxidant;
- b) measuring the amount of lipid peroxide and pyroglutamic acid in said sample;
- c) measuring the level of blood plasma glutathione;
- d) comparing the amount of lipid peroxide and pyroglutamic acid in said sample with that of a normal standard;
- e) comparing the level of blood plasma glutathione with that of a normal standard; and

wherein the presence of normal levels of lipid peroxide and pyroglutamic acid in said sample and the presence of normal levels of blood plasma glutathione are an indication of efficiency of utilization of the anti-oxidant.

15. The method of claim 14, wherein said subject receiving therapy with an anti-oxidant also experienced a reduction in immune cell number and/or function prior to the start of therapy with the anti-oxidant.

16. The method of claim 15, further comprising determining whether immune cell number and/or function is normalized in said subject, wherein said normalization is indicative of the utilization efficiency of said anti-oxidant.

17. The method of claim 16, wherein said immune cell is selected from the group consisting of a T cell, a B cell or a natural killer cell.

18. The method of claim 17, wherein said T cell is selected from the group consisting of a CD4+ T cell or a CD8+ T cell.

19. The method of claim 14, wherein said anti-oxidant comprises a formulation consisting of a glutathione precursor, wherein said glutathione precursor is IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

20. The method of claim 14, wherein the sample of body fluid is urine.

21. A method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is necessary to increase glutathione synthesis or re-synthesis in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of body fluid samples from a patient suspected of being in need of such treatment, wherein said body fluid samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days ;
- b) measuring the amount of lipid peroxide and pyroglutamic acid in said body fluid samples;
- c) comparing the amount of lipid peroxide and pyroglutamic acid in said body fluid samples with that of normal standards;
- d) measuring the amount of glutathione increase in blood samples;
- e) comparing the amount of glutathione in said blood samples with that of normal standards; and

wherein the normalization of lipid peroxide and pyroglutamic acid levels in said body fluid samples correlates with the synthesis or re-synthesis of glutathione in the patients receiving IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

22. A method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is necessary to reduce urine pyroglutamic acid in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of urine samples from a patient suspected of being in need of such treatment, wherein said samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days;
- b) measuring the amount of pyroglutamic acid in said samples;
- c) comparing the amount of pyroglutamic acid in said samples with that of a normal standard; and

wherein the reduction of pyroglutamic acid to normal levels in said samples correlates with the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to achieve a beneficial effect.

23. A method for determining the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is necessary to reduce urine lipid peroxide in a patient in need of such therapy, comprising the steps of:

- a) collecting a series of urine samples from a patient suspected of being in need of such treatment, wherein said samples are collected prior to the start of treatment, and daily after the start of treatment for about 14 days;
- b) measuring the amount of lipid peroxide in said samples;
- c) comparing the amount of lipid peroxide in said samples with that of a normal standard; and

wherein the reduction of lipid peroxide to normal levels in said samples correlates with the amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to achieve a beneficial effect.

24. A method for determining an orally anti-oxidative effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to diminish urine lipid peroxide and pyroglutamic acid levels and concurrently increase blood plasma glutathione levels, comprising the steps of:

- a) collecting blood plasma and urine samples prior to administration of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ and daily after the start of administration for about 14 days;
- b) measuring urine levels of lipid peroxide and pyroglutamic acid;

- c) measuring blood plasma glutathione levels;
- d) determining whether a decrease in lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels; and

wherein said correlation establishes an orally anti-oxidative effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

25. A method for establishing the interdependence of lipid peroxides, pyroglutamic acid, glutathione, and immune cell number and/or function in a subject suffering from oxidative stress, comprising the steps of:

- a) collecting a urine sample from a subject suspected of being under oxidative stress;
- b) assaying the urine for the presence of lipid peroxides and pyroglutamic acid;
- c) collecting a sample of whole blood;
- d) separating the cellular components from the liquid portion of whole blood;
- e) measuring glutathione in the liquid portion of whole blood obtained in step d);
- f) measuring the number of CD4+ and CD8+ T cells in the cellular component of whole blood from step d); and
- g) measuring the natural killer cell activity from the cellular component of whole blood obtained from step d);

wherein a finding of decreased plasma glutathione levels, an increase in urinary lipid peroxides and pyroglutamic acid, and a decrease in the number of CD4+ and CD8+ T cells and natural killer cell activity provides support for the interdependence of the level of oxidative stress in said subject and immune cell number and/or function.

26. A method for determining an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell activity in a subject suspected of experiencing oxidative stress, comprising the steps of:

- a) collecting whole blood samples prior to administration of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ and daily after the start of administration for about 14 days;

- b) separating the cellular component of the whole blood from the liquid component; and
- c) measuring the number of CD4+ and CD8+ T cells and natural killer cell activity using the cellular component from step b);

wherein a correlation between the dose of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ that is sufficient to normalize CD4+, CD8+ T cell numbers and natural killer cell activity establishes an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

27. A method for determining an orally anti-oxidative effective amount and an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ sufficient to normalize lipid peroxides, pyroglutamic acid and glutathione levels in a subject suspected of experiencing oxidative stress, wherein said normalization of lipid peroxides, pyroglutamic acid and glutathione levels results in immune enhancement, comprising the steps of:

- a) collecting whole blood and urine samples prior to administration of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ and daily after the start of administration for about 14 days;
- b) measuring urine levels of lipid peroxide and pyroglutamic acid;
- c) separating the cellular component of the whole blood from the liquid component;
- d) measuring blood plasma glutathione levels using the liquid component from step c);
- e) measuring the number of CD4+ and CD8+ T cells and natural killer cell activity using the cellular component from step c);
- f) determining whether a decrease in urinary lipid peroxide and pyroglutamic acid levels correlates with an increase in glutathione levels, and whether the normalization of the levels of all three of these products relates to a normalization of CD4+ and CD8+ T cell numbers and normalization of natural killer cell activity; and

wherein said correlation establishes an orally anti-oxidative effective amount and an immune enhancing effective amount of IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™.

28. The method of claim 27, wherein said correlation further establishes the interrelationship of lipid peroxides, pyroglutamic acid, glutathione and immune functions as compared to the level of oxidative stress in said subject which may result in depressed immune functions.

29. A kit for measuring oxidative stress in a subject comprising:

- a) a solid substrate containing immobilized binding partners specific for at least three markers for oxidative stress;
- b) either:
 - i) an enzyme conjugated second binding partner to the oxidative stress markers; or
 - ii) a biotinylated second binding partner to the oxidative stress markers;
- c) either:
 - i) the enzyme substrate and the developing reagents specific for the enzyme conjugated second binding partner from step b) i); or
 - ii) a streptavidin conjugated third binding partner specific for the second binding partner of step b) ii);
- d) buffers for washing and sample dilution;
- e) standards for each of the at least three markers of oxidative stress; and
- f) instructions for use of said kit.

30. The kit of claim 29, further comprising additional binding partners specific for cell surface markers for CD4+ T cells, CD8+ T cells and natural killer cells.

31. The kit of claim 29, wherein said markers of oxidative stress are selected from the group consisting of lipid peroxide, pyroglutamic acid and glutathione.

32. The kit of claim 29, wherein said binding partner is an antibody selected from the group consisting of a monoclonal antibody, a polyclonal antibody, a chimeric antibody, and any combination thereof.

33. A method for providing a course of therapy for an individual suspected or known to be suffering from oxidative stress comprising

- a) determining the identity and level of at least three markers of oxidative stress in a sample of body fluid from said individual in accordance with claim 29, said markers being indicative of the extent of oxidative stress; and
- b) selecting the appropriate course of therapy for said individual suffering from oxidative stress and the sequelae thereof.

34. The method of claim 33, which further includes administering said appropriate course of therapy to said individual.

35. A method for providing a course of therapy for an individual suspected or known to be suffering from oxidative stress and monitoring the success of said therapy comprising:

- a) determining the identity and level of at least three markers of oxidative stress in a sample of body fluid from said individual in accordance with claim 29, said marker indicative of the extent of oxidative stress;
- b) selecting the appropriate course of therapy for said individual suffering from said oxidative stress;
- c) administering said appropriate course of therapy to said individual; and

monitoring the success of said therapy by measuring a normalization in levels of said markers of oxidative stress.

36. The method of any of claims 33-35, wherein said course of therapy comprises administering IMMUNE FORMULATION 100™ or IMMUNE FORMULATION 200™ to said individual.